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December 16, 2014

VIA CM/ECF

The Honorable Paul S. Diamond
United States District Judge
Eastern District of Pennsylvania
601 Market Street
Philadelphia, Pennsylvania 19106

Re: *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Ltd. Co., et al.*, Civ. No. 12-3824 (Consolidated)

Dear Judge Diamond:

We write on behalf of Mylan Pharmaceuticals Inc. to notify the Court of a recent decision by Judge Robert W. Sweet of the U.S. District Court for the Southern District of New York in *The People of The State of New York v. Actavis, PLC and Forest Laboratories, LLC*, in a case regarding allegations of product hopping concerning Namenda, a drug that treats Alzheimer's. *See* Case No. 14-CV-7473 (RWS), Dkt. No. 70 (Dec. 10, 2014) (redacted public version of Amended Complaint). The Court last Thursday granted New York's motion for a preliminary injunction and ordered that Actavis and Forest ("*Namenda* Defendants") be enjoined from discontinuing the availability of the previous immediate release tablet form of Namenda until resolution of the litigation. *See id.* Dkt. No. 80 (Dec. 11, 2014) (redacted public version of opinion attached as Exhibit A to this letter). Defendant Actavis is the parent company of Forest and is the successor in interest of Warner Chilcott PLC, a Defendant in the *Doryx* case.

In *State of New York v. Actavis*, New York's Complaint alleged that the *Namenda* Defendants have engaged in an anticompetitive scheme to switch an immediate release tablet version of Namenda – which faces imminent generic competition – with an extended release capsule version of Namenda – which does not face any prospect of imminent generic competition. *Namenda*, Dkt. No. 51 at 1-5. New York further alleged that the anticompetitive effects of the conduct—the elimination of competition by a generic Namenda immediate release tablet—outweigh any possible, negligible procompetitive benefits that could result from the switch. *Id.*

New York moved for a preliminary injunction to enjoin the *Namenda* Defendants from removing the immediate release tablet from the market, and on December 11, 2014, the Court granted the motion in a sealed opinion, a redacted version of which has been released on the

public docket. Both the Court and New York rely heavily on the FTC Amicus Brief and the Scholars' Amicus Brief submitted in the *Doryx* litigation. *See* Ex. A Findings of Fact (FOF) ¶ 132 & Conclusions of Law (COL) at 116; *Namenda*, Dkt. No. 70 at 9-10, 13-14; *Namenda*, Dkt. No. 51 at 7, 10-11, 33-34, 44.

Judge Sweet's opinion strongly supports Mylan's Motion for Summary Judgment, Dkt. No. 509, and Mylan's Opposition to Defendants' Motion for Summary Judgment, Dkt. No. 576. Mylan argues in its summary judgment papers that the regulatory framework at issue here (including the Hatch-Waxman Act and state substitution laws) provides the efficient pathway for generic pharmaceutical entry and competition. Dkt. No. 509 at 4-6, 28-30, & 38-40; Dkt. No. 576 at 13-14; Dkt. No. 631 at 4-5 & 49-52. The *Namenda* Court accepts that argument. Ex. A FOF ¶¶ 22-36, ¶¶ 126-33, & ¶¶ 162-64 & COL at 116-18. Mylan further argues that Doryx and its AB-rated generic products comprise a relevant market, and that Defendants were able to harm competition in that market by strategically modifying the form and dosages of Doryx and eliminating existing forms from the market before meaningful AB-rated generic entry could occur. Dkt. No. 509 at 7-43; Dkt. No. 576 at 9-24; Dkt. No. 631 at 5-7 & 20-44. The *Namenda* Court made virtually identical findings to Mylan's arguments in *Doryx*. Ex. A FOF ¶¶ 56-167 & COL at 101-22.

The following table identifies key findings of the *Namenda* Court and the Mylan arguments to which that Court's findings are relevant:

Finding of the *Namenda* Court	***Namenda* Opinion Citation**	**Relevant Portions of Mylan's Briefing**
"State substitution laws operate to facilitate lower cost generics because they allow or require a pharmacist to provide a patient with a lower-cost generic drug without contacting the doctor to change the prescription."	FOF ¶ 28	Dkt. No. 509 at 5-6; Dkt. No. 576 at 6 & 13; Dkt. No. 631 at 33-34.
"An important limitation of generic substitution laws is that they generally permit a pharmacist to dispense a less-expensive generic drug instead of the branded drug only if the FDA approves the generic drug as 'AB-rated' to the branded drug."	FOF ¶ 28	Dkt. No. 509 at 5; Dkt. No. 576 at 6; Dkt. No. 631 at 33.
"Price competition at the pharmacy, facilitated by state generic substitution laws, is the principal means by which generics are able to compete in the United States."	FOF ¶¶ 30 & 129	Dkt. No. 509 at 5-6; Dkt. No. 576 at 6; Dkt. No. 631 at 33.

Finding of the *Namenda* Court	***Namenda* Opinion Citation**	**Relevant Portions of Mylan's Briefing**
"This tradeoff of longer exclusivity rights for branded manufacturers like Forest, in return for quick and effective generic entry after loss of exclusivity, is the fundamental premise behind the policies and procedures that Congress enacted in the Hatch-Waxman Act, and which New York and other states embraced in their substitution laws."	FOF ¶ 32	Dkt. No. 509 at 4-6; Dkt. No. 576 at 13-14; Dkt. No. 631 at 43.
"This AB-rated requirement, while intended to ensure therapeutic equivalence to the branded drug, provides an opportunity for branded manufacturers to game the system through a practice termed 'product hopping.'"	FOF ¶ 34	Dkt. No. 509 at 11, 36-37, & 40; Dkt. No. 576 at 13-14; Dkt. No. 631 at 8 & 36.
"As found above, the generic of the original version of the drug will not be 'AB-rated' to the follow-on branded drug. Thus, if physicians write prescriptions for the follow-on version instead of the original, the generic [] is not dispensed even if, in practice, the cost savings offered by the generic may outweigh any advantage offered by the new version of the branded drug."	FOF ¶ 34	Dkt. No. 509 at 39; Dkt. No. 576 at 5 & 13; Dkt. No. 631 at 4-5.
Single drug molecule found to be appropriate relevant market. Other drugs in the same therapeutic category were not considered substitutes because of differences in use and side effect profiles; a lack of positive cross-elasticity of demand; and defendants' own business strategy of maintaining monopoly profits through forced switch to follow-on product.	FOF ¶¶ 56-70; COL at 104	Dkt. No. 509 at 7-11 & 31-37; Dkt. No. 576 at 2-4 & 16-24; Dkt. No. 631 at 5-6 & 20-28.
Finding significant defendants' internal emails concerning the importance of switching patients to follow-on product to avoid imminent generic competition on original product.	FOF ¶¶ 72-76	Dkt. No. 509 at 16-17; Dkt. No. 576 at 5-6; Dkt. No. 631 at 36.
Finding significant that no studies had been done to show that follow-on product was more effective than original product.	FOF ¶¶ 82 & 86	Dkt. No. 509 at 22 & 46-47; Dkt. No. 576 at 41; Dkt. No. 631 at 10-11 & 13.
"If, however, Forest could get patients, physicians, and insurers to switch to Namenda XR [follow-on product] before the entry of generic memantine, Forest would be able to prevent manufacturers of generic Namenda IR [original product] from effectively competing for those patients."	FOF ¶ 89	Dkt. No. 509 at 12, 40-42, & 50-51; Dkt. No. 576 at 4-6; Dkt. No. 631 at 47.

Finding of the *Namenda* Court	***Namenda* Opinion Citation**	**Relevant Portions of Mylan's Briefing**
Rejecting defendants' attempts to establish legitimate procompetitive justifications for their forced switch as any potential cost savings or efficiencies were not quantified and unsupported by the contemporaneous business documents produced at the time defendants implemented their strategy.	FOF ¶¶ 113-25	Dkt. No. 509 at 21-26 & 43-52; Dkt. No. 576 at 8-9 & 31-41; Dkt. No. 631 at 6-7, 8-15, & 37-40.
"Defendants have stated that the very purpose of the limited distribution is to blunt generic competition and prevent the operation of state generic substitution laws."	FOF ¶ 114	Dkt. No. 509 at 11; Dkt. No. 576 at 4-5; Dkt. No. 631 at 6.
Forest's conversion from Namenda IR to Namenda XR prior to generic entry "would allow Forest to evade the application of [state substitution] laws and thus have a better chance of protecting its sales."	FOF ¶ 116	Dkt. No. 509 at 39; Dkt. No. 576 at 13-14; Dkt. No. 631 at 32-34.
"By implementing the limited distribution, Defendants game the generic substitution laws and prevent pharmacists from offering patients taking Namenda a lower-priced generic."	FOF ¶ 127	Dkt. No. 509 at 5-6 & 39; Dkt. No. 576 at 5 & 13-14; Dkt. No. 631 at 4-5.
"If pharmacists are not permitted to dispense a lower-priced generic instead of the brand without needing to get a new prescription from a doctor, generics are unlikely to be able to make substantial sales."	FOF ¶ 127	Dkt. No. 509 at 5-6; Dkt. No. 576 at 5 & 13-14; Dkt. No. 631 at 4-5.
"Generic products are typically not marketed to physicians or patients."	FOF ¶ 128	Dkt. No. 509 at 50-52; Dkt. No. 576 at 28-29; Dkt. No. 631 at 4, 17-18, & 42-43.
In selling its generic drug products, "Mylan does not have any direct relationship with patients, does not talk to doctors, and does not do direct-to-consumer advertising."	FOF ¶ 129	Dkt. No. 509 at 50-52; Dkt. No. 576 at 28-29; Dkt. No. 631 at 4, 17-18, & 42-43.
"Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete."	FOF ¶ 129	Dkt. No. 509 at 50-52; Dkt. No. 576 at 28-29; Dkt. No. 631 at 4, 17-18, & 42-43.
"[B]ecause the generic [firm] promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter."	FOF ¶ 129	Dkt. No. 509 at 51.

Finding of the *Namenda* Court	***Namenda* Opinion Citation**	**Relevant Portions of Mylan's Briefing**
"Generic manufacturers compete by selling products at a significant discount relative to their branded equivalents, and that discount typically increases as additional generic versions of a branded product enter the market."	FOF ¶ 131	Dkt. No. 509 at 9-10; Dkt. No. 576 at 28-29.
"Non-AB-rated generic drugs, such as generic memantine, cannot compete effectively for sales of a branded drug in the same class, such as Namenda XR, even if the price of the generic[] is much lower than the brand."	FOF ¶ 133	Dkt. No. 509 at 9-10; Dkt. No. 576 at 28-29.
"This reduction in the market opportunity for generics . . . is a substantial harm to competition."	FOF ¶ 146	Dkt. No. 509 at 38; Dkt. No. 576 at 11-12; Dkt. No. 631 at 31-32.
"Defendants' forced switch will also result in dramatically higher drug costs for insurers and patients, who might otherwise have chosen the less expensive generic."	FOF ¶ 153	Dkt. No. 509 at 28-30; Dkt. No. 576 at 7-8; Dkt. No. 631 at 6.
"Defendants are entitled to a just return on their investment in Namenda IR, but having enjoyed that return for over a decade, the law now requires them to allow generic competitors a fair opportunity to compete using state substitution laws."	FOF ¶ 162	Dkt. No. 509 at 1; Dkt. No. 576 at 1.
Rejecting argument that single drug product could not constitute its own relevant market simply because some industry classifications grouped it together with other drugs in a relevant therapeutic class.	COL at 105	Dkt. No. 509 at 34-37; Dkt. No. 576 at 19-24; Dkt. No. 631 at 20-21 & 24-26.
"Market power may also be established by considering evidence of anticompetitive effects of the challenged conduct [i.e., direct effects analysis]."	COL at 108	Dkt. No. 509 at 31-33; Dkt. No. 576 at 2-3 & 17-19; Dkt. No. 631 at 21-24.
Exclusionary conduct for a monopolization claim does not require "total foreclosure"; here, it was enough that "Defendants undertook to achieve significantly higher levels of conversion from IR to XR precisely by reducing generic competition, putting in place a limited distribution strategy to serve as an 'obstacle' to generic switching, thwarting state substitution laws."	COL at 117	Dkt. No. 509 at 39 & 51-52; Dkt. No. 576 at 29; Dkt. No. 631 at 33-34.
"In sum, the hard switch strategy constitutes an unreasonable restrain[t] on trade without a pro-competitive justification[.]"	COL at 125	Dkt. No. 509 at 40 & 42; Dkt. No. 576 at 43.

Finding of the *Namenda* Court	***Namenda* Opinion Citation**	**Relevant Portions of Mylan's Briefing**
"The hard switch violates the spirit of the Hatch-Waxman Act and the public policy underlying it."	COL at 134	Dkt. No. 509 at 39; Dkt. No. 576 at 13; Dkt. No. 631 at 32-34.

To the extent that the Court wishes to see the unredacted opinion or sealed evidence from the preliminary injunction proceedings, the Court may direct the *Namenda* Defendants (by way of Actavis, which is now the same corporate entity as Defendant Warner Chilcott and represented by the same counsel from White & Case LLP as in the Doryx litigation) to provide the materials to the Court under the protective order in this case.

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The Court now has before it three rigorous opinions (*TriCor*, *Suboxone*, and *Namenda*)[1] holding that product hopping like that at issue in *Doryx* should be evaluated under the rule of reason as articulated by cases like *Microsoft* and *Dentsply*, that the branded and AB-rated generic versions of a single pharmaceutical product may comprise a relevant market over which the brand company can exercise monopoly power, and that exclusion of AB-rated generic competition can still harm competition despite the theoretical availability of alternative means of (non-AB-rated) market entry. Defendants' legal positions on summary judgment are thus untenable, and the factual record demonstrates beyond serious dispute that Mylan can establish each element of its antitrust claims. The Court should therefore grant Mylan's motion for summary judgment as to Defendants' antitrust liability, or at a minimum expeditiously deny Defendants' motion for summary judgment and schedule the case for a trial on the merits.

[1] As discussed in prior filings, the *Prilosec* cases (the only other cases on product hopping) are not on-point because the branded manufacturer made no attempt to withdraw Prilosec from the market and simply made a new over-the-counter product available in addition to the existing prescription product. *See* Dkt. No. 111 at 21-22 & n.6; Dkt. No. 631 at 31 & 34. And in any event, the main judicial opinion from those cases endorses rule of reason scrutiny of pharmaceutical product switches. *See Walgreen Co. v. AstraZeneca Pharms. LP*, 534 F. Supp. 2d 146, 150-51 (D.D.C. 2008).

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